

## **REMARKS**

### ***Status of the Claims***

Claims 1-23, 25-27, and 30-37 are pending. Claims 1-4, 12, 14, 16-17, and 19 are amended. Claims 20-23 and 25-27 are withdrawn from consideration.<sup>2</sup> New claims 30-37 are added. Support for the claim amendments may be found throughout the specification and the claims as originally filed.<sup>3</sup> No new matter is added.

### ***Specification***

The USPTO objects to the specification because it contains embedded hyperlinks and/or other forms of browser-executable code.

The specification has been amended to delete the embedded hyperlinks and/or other form of browser-executable codes. Accordingly, this objection is moot.

### ***Interview Summary Under 37 C.F.R. § 1.133***

On November 2, 2009, Applicants' representatives, Supervisory Examiner Anne Marie Grunberg, and Examiner Brent Page conducted an interview for this application and Application No. 10/591,428 ("the '428 application").

The Examiners agreed that the rejection under 35 U.S.C. § 102 (b) over Frohberg in light of Ritte should be withdrawn, if the claims recite that a foreign molecule reduces the expression of an endogenous nucleic acid molecule that encodes an OK1 protein (e.g., a foreign nucleic acid molecule that encodes the OK1 protein). The Examiners also agreed that Kikuchi does not disclose the starch phenotypes of the protein activity of SEQ ID NO: 22133.<sup>4</sup>

Applicants thank Examiners Grunberg and Page for conducting the interview and the courtesies extended by the Examiners during the interview.

---

<sup>2</sup> Applicants respectfully request rejoinder of these claims when allowable claims are identified. *See* M.P.E.P. §§ 821.04(a) and (b).

<sup>3</sup> *See, e.g.*, Specification, ¶¶ [0034], [0098], [0100], [0101], [0117], [0122], [0191], and [0192].

<sup>4</sup> *See* Interview Summary; *see also* Interview Summary for the '428 application ("It was agreed that the pending reference listing over 20,000 sequences without a reduction to practice was an obviousness under 103(a). It was also agreed that the prior art did not select the claimed sequence on the basis of starch phenotype or with the knowledge of the resultant protein activity.").

***Rejections Under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph***

Claims 12-15 stand rejected under 35 U.S.C. § 112, second paragraph, because it is allegedly not clear whether claim 12 should recite an “increased” or “reduced” OK1 protein activity.<sup>5</sup>

Claim 12 has been amended to recite a “reduced” activity. As such, this rejection is moot.

***Rejections Under 35 U.S.C. § 112, 1<sup>st</sup> Paragraph***

Claims 12-15 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, the USPTO contends that the specification does not support a “method of producing a plant with reduced OK1 protein activity by a genetic modification that increases the activity of OK1.”<sup>6</sup>

Claim 12 has been amended to recite “genetically modifying a plant cell by introducing at least one foreign nucleic acid molecule that reduces the expression of at least one endogenous gene encoding an OK1 protein into said plant cell, wherein said genetically modified plant cell has a reduced activity of at least one OK1 protein.” This amendment is supported by the application as originally filed.<sup>7</sup> In view of the amendment, Applicants respectfully submit this rejection is moot.

Claims 12-15 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement. Specifically, the USPTO contends that the specification does not provide guidance that would enable one to practice a “method of producing a plant with reduced OK1 protein activity by a genetic modification that increases the activity of OK1.”<sup>8</sup>

Claim 12 has been amended to recite “genetically modifying a plant cell by introducing at least one foreign nucleic acid molecule that reduces the expression of at least one endogenous gene encoding an OK1 protein into said plant cell, wherein said genetically modified plant cell has a reduced activity of at least one OK1 protein.” The specification provides guidance that would

---

<sup>5</sup> See Office Action, pages 3-4.

<sup>6</sup> See *id.* at pages 4-5.

<sup>7</sup> See, e.g., Specification, ¶¶ [0034], [0098], [0191], and [0192].

<sup>8</sup> See Office Action, page 5.

enable one of skill to practice this method.<sup>9</sup> In view of the amendment, Applicants respectfully submit this rejection is moot.

***Rejections Under 35 U.S.C. § 102***

Claims 1-2, 4-19, and 29 stand rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by Frohberg (U.S. Pat. No. 6,521,816, “Frohberg”) in light of Ritte et al. (FEBS Letters 580:4872-4876, 2006, “Ritte”).

As amended, the claims are directed to, *inter alia*, plant cells and plants comprising at least one foreign nucleic acid molecule that reduces the expression of at least one endogenous gene encoding an OK1 protein. As discussed below, Frohberg does not teach or suggest plant cells or plants comprising such foreign nucleic acid molecules.

**A. Frohberg does not teach an endogenous OK1 gene, let alone a foreign nucleic acid molecule that reduces expression of an endogenous OK1 gene.**

To reduce the expression of a specific sequence (i.e., an endogenous gene encoding an OK1 protein), one must know the sequence whose expression is to be reduced. For example, to reduce the expression of an endogenous OK1 gene using any of the technologies described in claim 4 (e.g., antisense, co-suppression, RNAi), one would require sequence information of an endogenous OK1 gene. Frohberg does not teach the sequence of an endogenous gene encoding an OK1 protein or a nucleic acid molecule that reduces expression of an endogenous OK1 gene. Rather, Frohberg relates to foreign nucleic acid molecules that reduce the expression of at least one endogenous gene encoding an R1 protein. Accordingly, because Frohberg does not teach an endogenous OK1 gene or a foreign nucleic acid molecule that reduces the expression of an endogenous OK1 gene, Frohberg does not anticipate the claims.

**B. A reduction in OK1 activity does not necessarily mean a reduction in the expression of an OK1 gene.**

The USPTO asserts that OK1 protein activity depends on previous phosphorylation of starch by R1 proteins because phosphorylated starch produced by the catalysis of an R1 protein represents the substrate for further phosphorylation by an OK1 protein.<sup>10</sup> As such, the USPTO

---

<sup>9</sup> See, e.g., Specification, ¶¶ [0034], [0098], [0191], and [0192]; see also Examples.

<sup>10</sup> See *id.* Applicants respectfully disagree with the USPTO’s assertion although note that pre-phosphorylation by R1 proteins is shown in the application by way of example. Applicants submit that enzymes other than R1 proteins could introduce phosphate into starch and thereby produce the phosphorylated substrate for OK1 proteins.

contends that the reduction of R1 protein activity in Frohberg's plants reduces the amount of substrate for an OK1 protein and thereby its activity in the plants.

Applicants respectfully disagree. Indeed, as discussed below, even assuming a reduction in R1 activity leads to a reduction of OK1 activity, as the USPTO contends<sup>11</sup> but Applicants do not concede, it does not necessarily follow that a reduction in R1 activity reduces the expression of an endogenous OK1 gene.

First, Frohberg's plants have a reduced expression of R1 proteins because transcription and/or translation is reduced for an R1 protein. Frohberg's plants do not, however, have a reduced expression of OK1 proteins because transcription and/or translation is not reduced for an OK1 protein in these plants. As such, the amount of OK1 protein is not reduced in Frohberg's plants.

Second, the specification demonstrates a reduction in OK1 protein activity without a reduction in the amount of OK1 protein produced. In particular, the specification teaches that OK1 proteins, although present in a reaction, do not introduce a significant amount of phosphate into non-phosphorylated starch.<sup>12</sup> In Example 6, Preparation A contains the same amount of OK1 protein as preparations B and C, respectively, but preparation A contains **non**-phosphorylated starch, whereas preparation B contains phosphorylated starch and preparation C is a control containing phosphorylated starch, but **no** protein. The results, summarized in Table 1 and FIG. 3, demonstrate that although OK1 protein is present in an adequate amount in preparation A, it has a reduced activity on non-phosphorylated starch.

According to the USPTO, the reduction in R1 activity, as taught by Frohberg, leads to a reduction of OK1 activity. As discussed above, however, the expression and amount of OK1 proteins are not reduced in Frohberg's plants, nor does a reduction in OK1 activity necessarily result in a reduction of the expression and amount of OK1 proteins. Accordingly, because a reduction in R1 activity does not necessarily result in a reduction in the expression of an endogenous OK1 gene, Frohberg does not anticipate any of the claims.

In view of the foregoing, Applicants respectfully request withdrawal of this rejection.

---

<sup>11</sup> See Office Action, pages 6-7 (asserting that OK1 activity is "strictly dependent on phosphorylation of the starch by GWD (R1)" and that "the reduction in phosphorylated starch would reduce the activity of OK1.").

<sup>12</sup> See Specification, Example 6.

Claims 1-7, 9-11, 16-19, and 29 stand rejected under 35 U.S.C. § 102(e), as allegedly being anticipated by U.S. 20060123505 ("Kikuchi").

As discussed above, the claims relate to plant cells and plants comprising foreign nucleic acid molecules that reduce the expression of an endogenous OK1 gene.

The USPTO asserts that Kikuchi teaches SEQ ID NO: 22133 (which purportedly encodes the OK1 protein), as well as antisense, ribozyme, RNAi, or co-suppression constructs.<sup>13</sup> As such, the USPTO contends that Kikuchi anticipates the claims.

Applicants respectfully disagree.

Kikuchi discloses 28,469 cDNA sequences.<sup>14</sup> Kikuchi does not disclose that any of these sequences is involved in starch metabolism or has OK 1 activity, let alone disclose a foreign nucleic acid molecule that reduces the expression of any of these sequences. Indeed, Kikuchi is completely silent with respect to the activity of SEQ ID NO: 22133.<sup>15</sup> Kikuchi also fails to provide any guidance to one of skill in the art to (1) select SEQ ID NO: 22133 out of the 28,469 sequences; and (2) design or obtain a foreign nucleic molecule that reduces the expression of SEQ ID NO: 22133. To be sure, Kikuchi does not suggest any preference for SEQ ID NO: 22133, or for reducing the expression of this sequence in a plant cell.

During the interview, Applicants' representatives and the Examiners discussed Kikuchi in connection with the '428 application. The Examiners agreed that because Kikuchi does not reduce to practice a plant cell comprising SEQ ID NO: 22133, Kikuchi did not anticipate the claims of the '428 application.<sup>16</sup> The Examiners also agreed there is no reason to select SEQ ID NO: 22133 from the thousands of sequences disclosed and introduce this sequence into a plant cell to obtain a desired starch phenotype.<sup>17</sup>

---

<sup>13</sup> See Office Action, page 8.

<sup>14</sup> See Kikuchi, ¶ [0011].

<sup>15</sup> See, e.g., Interview Summary ("Kikuchi et al. do not disclose the starch phenotypes of protein activity of the disclosed sequence, SEQ ID NO: 22133")

<sup>16</sup> See Interview Summary for the '428 application ("It was agreed that the pending reference listing over 20,000 sequences without a reduction to practice was an obviousness under 103(a).")

<sup>17</sup> See *id.* ("It was also agreed that the prior art did not select the claimed sequence on the basis of starch phenotype or with the knowledge of the resultant protein activity.")

Likewise, because Kikuchi does not reduce to practice a plant cell comprising a foreign nucleic acid molecule that reduces the expression of SEQ ID NO: 22133, Kikuchi does not anticipate the instant claims. Moreover, there is no reason to select SEQ ID NO: 22133 from the thousands of sequences disclosed and design or obtain a foreign nucleic molecule that reduces the expression of SEQ ID NO: 22133. Accordingly, Kikuchi does not anticipate or render obvious any of the claims.

In view of the foregoing, Applicants respectfully request withdrawal of this rejection.

***Double Patenting***

Claim 12 stands provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of co-pending U.S. Application No. 10/591,428.

Applicants respectfully request that this rejection be held in abeyance until allowable subject matter is identified.

### CONCLUSION

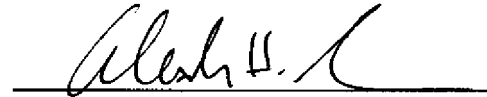
Applicants respectfully submit that the present application is in condition for examination.  
Early and favorable action by the Examiner is earnestly solicited.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Dated: November 24, 2009

By:



Robert M. Schulman  
Registration No. 31,196

Alexander H. Spiegler  
Registration No. 56,625

HUNTON & WILLIAMS LLP  
1900 K Street, N.W.  
Washington, D.C. 20006-1109  
Telephone: (202) 955-1500  
**Direct Dial: (202) 955-1899**  
Facsimile: (202) 778-2201  
Direct dial: (202) 955-1899